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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,592	10/03/2000	Andrew W. Murray	215538.00210	5305

27160 7590 06/02/2004

PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,592	MURRAY, ANDREW W.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, as specifically drawn to a method of identifying a drug that inhibits the growth or replication of a cell having a mutated MAD2 gene, classified in class 435, subclass 4.
(Upon election of Group I, applicant must further choose ONE secondary gene from those listed in Claim 7, as each secondary gene is a distinct invention, NOT a species)

II. Claims 8-10, as specifically drawn to a method of identifying a compound useful in the treatment of tumor cells having a mutated MAD2 gene, classified in class 435, subclass 4.
(Upon election of Group II, applicant must further choose ONE secondary gene from those listed in Claim 10, as each secondary gene is a distinct invention, NOT a species)

III. Claim 11, as specifically drawn to a screening assay system for identifying a drug, classified in class 436, subclass 63.

IV. Claim 12, as specifically drawn to a method of screening for the presence of benign or malignant cell growth in a tissue sample, classified in class 435, subclass 6.

V. Claims 13-14, as specifically drawn to a product capable of selectively interacting with a gene in a target cell, wherein said product is a pharmaceutical composition, classified in class 514, subclass 1.

(Upon election of Group V, applicant must further choose ONE drug comprised in the pharmaceutical composition from those listed in Claim 14, as each drug is a distinct invention, NOT a species)

Please choose from Claim 14 ONE of the following:

1) Oligonucleotide

2) Gene products (Proteins)

3) Small molecule

4) Peptide mimetic

VI. Claims 15-18, as specifically drawn to a method of treatment for a human or animal hosting a disease associated with MAD2 with a pharmaceutical composition, classified in class 424, subclass 9.2.

VII. Claim 19, as specifically drawn to a method of treating cancer cells having abnormal accumulations of MAD2 with a pharmaceutical composition capable of selectively interacting with a secondary gene, classified in class 514, subclass 1.0. **(Upon election of Group VII, applicant must further choose ONE secondary gene from those listed in Claim 19, as each secondary gene is a distinct invention, NOT a species)**

VIII. Claims 20-22, as specifically drawn to a recombinant eukaryotic cell comprising at least one secondary gene and at least one primary gene MAD2 , classified in class 435, subclass 325.
(Upon election of Group VIII, applicant must further choose ONE secondary gene from those listed in Claim 21, as each secondary gene is a distinct invention, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

The invention of Groups I-II, IV, VI-VII are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response

variables, and criteria for success. For example, Group I is drawn specifically to a method of identifying a drug that inhibits the growth or replication of a cell having a mutated MAD2 gene, whereas Group VII is drawn to a method of treating a disease associated with MAD2 mutation. Furthermore, Group I is specifically drawn to method of identifying a drug that inhibits the growth or replication of a cell having a mutated MAD2 gene, whereas Group II is a method of identifying a compound useful in the treatment of cancer cells.

The inventions of Groups III, V, and VIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group V is drawn to a pharmaceutical composition, whereas Group VIII is drawn to a recombinant eukaryotic cell.

The inventions of Group V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the drug can be used to produce an antibody for selectively targeting mutated MAD2 gene products.

The invention of Groups III and VIII and the methods of Groups I-II, IV, VI-VII are not at all related because the cells and screening assay system of Groups III and VIII are not used in any of the methods of Groups I-II, IV, VI-VII .

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species Election

Groups VI(Claims 16-18) are generic to a plurality of disclosed patentably distinct species comprising a disease associated with MAD2 such as: Apudoma, choristoma, branchioma

... yeast infection, breast cancer, etc. **which differ at least in etiology, pathology, and mechanisms.**

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant transverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior are, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable,

withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER